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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,905	10/25/2003	Kunapuli T. Madhusudhan	UAMS-I02-236	8704
34607	7590	11/09/2005	EXAMINER	
ANGELA FOSTER, PHD, ESQ. 2906 BIRCHWOOD COURT NORTH BRUNSWICK, NJ 08902-3933			BERTAGNA, ANGELA MARIE	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 11/09/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/692,905	MADHUSUDHAN, KUNAPULI T.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Angela Bertagna	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7 and 42-46 is/are allowed.
- 6) ☒ Claim(s) 8-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities: the "Detailed Description of the Drawings" section should be titled "Brief Description of the Drawings".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8 - 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 8 - 41 are confusing because the independent claims (8, 13, 19, 24, 30 and 36) recite the limitation "said nucleic acid products amplified from step (b)" in step (c) of the claimed methods. There is insufficient antecedent basis for this limitation in the claims, because step (b) recites "amplifying nucleic acid present in said sample using primer sets".

5. Claim 33 is confusing because it recites the limitation "said MOTT (mycobacteria other than tuberculosis) is selected from the group consisting of..." in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim, because the independent claim (30) recites a method for detection and differentiation of

*Mycobacterium tuberculosis* (MTB) and *Mycobacteria chelonae*, but does not include MOTT.

***Allowable Subject Matter***

6. Claims 1 – 7 and 42 – 46 are allowed.
7. Claims 8 - 41 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.
8. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).
9. The following is a statement of reasons for the indication of allowable subject matter:

Claims 1 - 46 are drawn to methods and kits for the detection and specific identification of MTB, MOTT, and *Mycobacteria chelonae*. The claimed methods and kits utilize three claimed primer sets (SEQ ID Nos: 1-6) to selectively amplify the different species of mycobacteria. The primer sets defined in SEQ ID Nos: 1-6 were not found or suggested in the prior art.

Sandhu et al. (US Patent No. 5,731,150) disclose the use of a primer set (claimed SEQ ID Nos: 1 and 2) to detect MTB. SEQ ID No: 1 of the instant application

directly follows SEQ ID No: 1 of Sandhu et al. but shows no overlap. SEQ ID No: 2 of the instant application shows an overlap of nine nucleotides with SEQ ID No: 2 of Sandhu et al. However, Sandhu et al. do not provide suggestion or motivation to shift the primer sequences in such a way as to achieve the instant claimed methods.

Guesdon et al. (US Patent No. 5,776,693) disclose primers for specific detection of MTB. One of these primers (SEQ ID No: 3) contains the complete sequence of SEQ. ID No: 2 of the instant application. However, SEQ ID No: 1 is not disclosed in Guesdon et al. nor is suggestion or motivation provided for the use of SEQ ID No: 1 in combination with SEQ ID No: 2 as a primer set for specific detection of MTB.

Kim et al. (US Patent No. 6,670,130 B1) disclose oligonucleotide primers or probes for specific detection of mycobacteria. SEQ ID Nos: 39 and 45 of Kim et al. show overlap with SEQ ID Nos: 5 and 6 of the instant application by 17 and 6 nucleotides, respectively. However, Kim et al. do not provide suggestion or motivation for shifting the primer sequences in such a way as to achieve the claimed methods.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is (571) 272-8291. The examiner can normally be reached on M-F 7:30-5 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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~~KENNETH R. HORLICK, PH.D.~~  
~~PRIMARY EXAMINER~~  
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11/7/05